

## **REMARKS**

Claims 1-3 were rejected in the Office Action mailed August 15, 2001, and claims 2 and 3 were objected to. By this Reply, claims 1-3 have been amended, claims 4-15 have been added, and no claims have been canceled. Claims 1-15 are currently pending in this application.

### **Information Disclosure Statement**

Applicant notes the Examiner's comments concerning the Information Disclosure Statement filed on July 18, 2001. An Information Disclosure Statement has been filed with this response which contains an English abstract of CH 507727 and English equivalent GB 1,169,523.

### **Specification**

The Examiner has stated that "The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper."

Applicant respectfully submits that the Examiner has misunderstood the importance of the material incorporated by reference herein. Applicant believes that no material incorporated by reference herein is "essential material, and that the specification stands alone as a fully enabling document. If it should be apparent that "essential material" is missing from the disclosure and needs to be incorporated, applicants will bodily incorporate said material.

In addition, the disclosure has been objected to on the grounds that "[t]he disclosure makes reference to Figures 1, 2 and 3, but no drawings were filed with the present application." This concern has been addressed by the addition of the figures of this application (See below).

### **Drawings**

Applicant has added Figures 1-3 to the specification. A copy of the priority application DE 19726164.7 is enclosed herein to demonstrate that these figures are not new matter since they were incorporated by reference. To the extent that they were "essential material," they are now bodily incorporated.

### **Claim Rejections Under 35 U.S.C. §112**

Claims 2 and 3 have been rejected under 35 U.S.C. §112, second paragraph, on the grounds that claims 2 and 3 "[p]rovide for the use of a monolithic sorbent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what methods/process applicant is intending to encompass."

This concern has been addressed by clarifying amendments to claims 2-3, which do not represent a change in claim scope.

### **Claims Rejections Under 35 U.S.C. §101**

Claims 2 and 3 have been rejected under 35 U.S.C. §101 on the grounds that "the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process."

This concern has been addressed by clarifying amendments to claims 2-3, which do not represent a change in claim scope.

### **Claim Rejections Under 35 U.S.C. §102/103**

Claims 1-3 have been rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Frechet et al. (USP 5,334,310). Applicant respectfully submits that the subject matter of these claims, particularly as amended, is unanticipated and non-obvious over this reference.

First, it is respectfully submitted that Frechet et al. does not anticipate the subject matter of the claims. Amended independent claim 1 is directed to encased ceramic mouldings. Frechet et al. does not disclose the presence or use of ceramic mouldings. Therefore, Frechet et al. does not disclose each feature of the invention as required under Section 102.

Further, it is respectfully submitted that the subject matter of the claims is not obvious in view of Frechet et al..

The instant invention is directed to encased monolithic sorbents based on ceramic (inorganic) mouldings (page 1, lines 37-38, and page 6, lines 1-3 and lines 24-35). The present

invention provides encased ceramic mouldings made with a novel method which addresses problems, which are present in the art, of encasing rigid mouldings. Rather than providing a casing and attempting to pack the sorbent into the casing, a rigid sorbent is provided and a pressure-stable casing is generated on the sorbent by one of several methods (page 6, line 18 - page 7, line 2).

Frechet et al., by contrast, is directed to polymeric organic separation media for chromatography (Col. 2, lines 60-61). The column has at least one plug of a continuous macroporous polymer material disposed therein (Col. 3, lines 9-14; See also, col. 3, lines 41-50 and 60-63).

The process for producing the column of Frechet et al. is carried out by using a simple polymerization process within the tube of the column to make the packing therein, and generally comprises (1) adding to a rigid tube sealed at both ends a deaerated polymerizable mixture containing a porogen, (2) polymerizing the mixture to form a macroporous polymer plug, and (3) washing the plug (Col. 5, lines 13-19; See also, col. 3, lines 58-63, col. 4, lines 28-32 and col. 5, lines 13-19. In other words, the column is created by generation of the polymeric sorbent within the tube, where it remains after synthesis.

First, because Frechet et al. does not disclose or provide a teaching suggesting an encased ceramic moulding as herein, it is respectfully submitted that Frechet et al fails to provide even a *prima facie* case of obviousness against the invention herein. There is no motivation in Frechet et al. to modify its polymeric sorbent to a ceramic moulding material.

Further, it is respectfully submitted that because Frechet et al. is directed to dealing with the problem of generating a continuous macroporous polymer material rather than that of functionalizing ceramic mouldings, Frechet et al. provides no disclosure or teaching for encasing ceramic mouldings as herein.

The ceramic mouldings of the present invention cannot be produced within the tube of the column, as is taught in Frechet et al. because the green compact of such a moulding shrinks during subsequent firing and calcination steps (Specification, page 1, lines 18-20). It is respectfully submitted on information and belief that due to the shrinking during synthesis of the mouldings, hollow space is generated between the sorbent and the casing, such that if one of

ordinary skill used this method of construction for a chromatography column, the eluent would run along the hollow space during use instead of passing through the sorbent. Therefore, the in-tube polymerization method as disclosed and taught in Frechet et al. could not be used for encasing the rigid ceramic mouldings herein. Accordingly, the disclosure and teachings of Frechet et al. do not render the instant invention obvious.

Thus, this rejection should be withdrawn.

Claims 1-3 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Nakanishi et al. (USP 5,624,875) in view of Schick (USP 5,482,628).

Applicant respectfully submits that the subject matter of these claims is non-obvious over the references.

Nakanishi et al. is directed to rigid ceramic mouldings for use in chromatography. (Col. 2, line 61, col. 3, line 2). Nakanishi et al. provides no teaching or disclosure concerning encasing the mouldings with a casing. Indeed, Nakanishi et al. does not even provide a teaching or disclosure concerning the difficulties arising from the necessity of encasing the rigid mouldings after synthesis, thereby providing no motivation to one of ordinary skill to seek further references to combine with Nakanishi et al..

Schick is directed to a biocompatible column for liquid chromatography (Abstract, line 1 and col. 4, lines 36-39) comprising an inner plastic tube and an outer metal tube (Col. 5, lines 39-44 and claim 1). The column is packed with a particulate material (Col. 1, lines 29-32 and col. 8, lines 58-61). As in Frechet et al., a tube is provided, into which separation material is placed. It is respectfully submitted that this method cannot be applied to ceramic mouldings to arrive at the instant invention.

First, it is respectfully submitted that the sorbent material of the present invention cannot be packed into the column of Schick as taught by Schick because the rigidity and solid form of the ceramic mouldings would be incompatible with such a packing method.

Further, the ceramic mouldings of the present invention could also not be produced within the column of Schick. As discussed herein, the green compact of such a moulding shrinks during subsequent firing and calcination steps (Specification, page 1, lines 18-20), and as stated

herein, on information and belief, this method results in shrinking during synthesis of the mouldings and generation of hollow space.

Schick offers no teaching or disclosure as to how to combine the tube therein with the ceramic moulding of Nakanishi et al. to arrive at the instant invention. Applicant respectfully submits that a combination of these references would be impermissible hindsight, and that no fair combination of the references could result in the instant invention.

Accordingly, it is respectfully requested that this rejection be withdrawn.

### **Amendment to specification/claim**

The specification has been amended, and the abstract replaced, to change the description of the diameter of the mesopores of the ceramic moulding from "2 and 100 nm" to "2 to 100nm". This amendment is to correct an obvious error appearing in the application. The obviousness of this error is reflected in WO 95/03256 (mentioned in the specification, on page 2, line 25) which discloses a median value for ceramic sorbents like those herein of 2 to 100nm at page 4, line 22 therein.

### **Added Claims**

The subject matter of independent claim 1 has been divided into amended claim 1 and added claim 4.

Support for claim 5 can be found in the specification at page 6, line 1-page 7, line 13.

Support for claims 6-7 can be found in the specification at page 6, lines 1-12.

Support for claims 8-9 can be found in the specification at page 6, lines 14-22.

Support for claim 10 can be found in the specification at page 6, lines 24-30.

Support for claims 11-12 can be found in the specification at page 6, line 34-page 7, line 2).

Support for claim 13 can be found in the specification at page 7, lines 5-13.

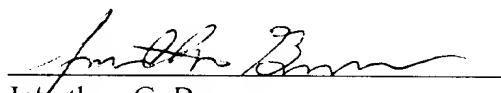
Support for claims 14-15 can be found in the specification at page 8, lines 27-29.

In view of the foregoing, it is respectfully submitted that this application is in condition for immediate allowance. If there are any issues which may expedited by a telephone call, the Examiner is cordially invited to contact counsel for applicant at the number indicated below.

Respectfully submitted,



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**Date:** January 15, 2002



**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION**

Please amend the indicated paragraphs of the specification as follows:

Page 1, line 37-page 2, line 7

The invention relates to encased monolithic sorbents based on porous mouldings, in particular those which have interconnected macropores and mesopores in the walls of the macropores, where the diameter of the macropores has a median value of greater than 0.1  $\mu\text{m}$  and where the diameter of the mesopores has a median value of 2 ~~and to~~ 100 nm, the outer surface of said monolithic sorbent being surrounded in a liquid-impermeable manner by a pressure-resistant plastic casing.

Page 2, lines 22-36

Monolithic sorbents are known in principle from the literature; they include, in particular, porous ceramic mouldings, as disclosed in WO 94/19 687 and WO 95/03 256. The term monolithic sorbents in the broader sense also includes mouldings made from polymers, as described by F. Svec and J. M. Frechet (1992) *Anal. Chem.* **64**, pages 820 – 822, and by S. Hjerten et al. (1989) *J. Chromatogr.* **473**, pages 273 – 275. Particular preference is given to monolithic sorbents based on porous mouldings which have interconnected macropores and mesopores in the walls of the macropores, where the diameter of the macropores has a median value of greater than 0.1  $\mu\text{m}$  and where the diameter of the mesopores has a median value of 2 ~~and to~~ 100 nm.

## IN THE CLAIMS

Please amend claims 1-3 as follows:

1. (Amended) An encased ~~Encased~~ monolithic sorbent ~~based on comprising at least one porous ceramic moulding mouldings which have interconnected macropores and mesopores in the walls of the macropores, where the diameter of the macropores has a median value of greater than 0.1 µm and where the diameter of the mesopores has a median value of 2 and 100 nm, characterized in that wherein~~ the outer surface of said monolithic sorbent is surrounded in a liquid-impermeable manner by a pressure-resistant plastic casing.
  
2. (Amended) ~~Use of a monolithic sorbent according to claim 1 in a~~  
~~A chromatographic column or a chromatographic cartridge comprising a monolithic sorbent~~  
~~according to claim 1.~~
  
3. (Amended) ~~Use of a monolithic sorbent according to claim 1 in the~~  
~~A method of chromatographic separation of at least two substances comprising:~~
  - a) ~~providing the two substances, and~~
  - b) ~~separating the two substances using a monolithic sorbent according to claim 1.~~